10

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,925	10/15/2003	Dwight L. Anderson	110.01840101	7050

26813 7590 12/16/2004

MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581415
MINNEAPOLIS, MN 55458

EXAMINER
LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/685,925	**Applicant(s)** ANDERSON ET AL.
	Examiner Zachariah Lucas	**Art Unit** 1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *9-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4-5-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, and the species represented by the pathogen Salmonella spp., and the substrate "magnetic bead" in the reply filed on October 22, 2004 is cknowledged. The traversal is on the ground(s) that there is no undue burden in the examination of the different groups of inventions. This is not found persuasive because the different groups related to different methods, which perform different functions, and have different modes of operation. Additionally, a search for the methods according to one group would not be coextensive with the search for the other group.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 9-12 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 22, 2004.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on April 5, 2004, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

4. It is noted that the following references are in a foreign language, and is accompanied only by an English translation of the claims or abstract. The references have therefore been considered only to the extent of the disclosure in the English language.

EP 0 781 349, WO 89/03878, WO 90/04037, and WO 96/17961.

5. It is additionally noted that:

only the Table of Contents, the Preface, and one page of the introduction have been provided for the Adams reference identified on page 3 of the IDS;

only the preface and Table of Contents have been supplied for the Hastings et al. reference on page 6 of the IDS; and

only the Table of Contents has been provided for the Karam et al. reference identified on page 7 of the IDS.

The references have therefore been considered only to the extent of the submitted pages.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim reads on the method of claim 13 "wherein the binding agent is biotic and the ligand for the binding agent is streptavidin." However, while claim 15 is further limiting

"the binding agent," there are two binding agents present in the method of claim 13: a binding agent for the bacteriophage introduced into the sample, and a binding agent for the new bacteriophage. It is unclear if the binding agent identified in claim 15 is intended to be the first of these binding agents (i.e. not a binding agent for the new bacteriophage), or the latter of the agents.

Clarification is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-6 rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Wilson (U.S. 5,985,596- of record in the April 2004 IDS) in view of Olsvik et al. (Clin Microbiol Rev 7:43-54- of record in the April 2004 IDS), and Sun et al. (J Indust Microbiol Biotech 25: 273-75- of record in the April 2004 IDS). These claims read on a method for detecting bacterial cells in a sample comprising incubating the sample with a first bacteriophage ("phage") comprising a binding agent and which are specific to the bacterial cells, removing the first phage which did not infect cells from the sample by contacting the sample with a substrate comprising a ligand for the binding agent, and detecting new (progeny) phage in the sample, wherein the presence of such new phage indicate the presence of the target bacterial cells.

Wilson teaches a method for the detection of bacterial cells comprising the steps of incubating a sample with a first bacterium, removing or inactivating the first bacterium, and detecting the formation of plaques in a bacterial culture, the presence of such plaques indicating the infection of cells in the sample, and therefore the presence of the target bacterial cells. Column 1. The reference teaches that such methods may be used for the detection of bacteria such a Salmonella spp. Column 1, lines 58-60. However, while the reference teaches that the first phage may be either removed or inactivated, the reference does not teach the claimed method of removing the first phage from the sample.

The art teaches that the use of magnetic beads was a known method for the capture and removal of target compounds from compositions. See e.g., Olsvik et al. (teaching the use of such beads for the isolation and removal of biological structures from suspensions). See also, "BioMag system" datasheet (of record on page 4 of the April 2004IDS). In addition to teaching that the beads may be used in methods for the separation of cells and antibodies, Olsvik also teaches that such methods have been shown to work with respect to viruses. Page 43. Because Olsvik states that the methods have proven useful in the detection of virus, and teaches that the same methods are known in the art for the removal of compounds from suspension, it would have been obvious to those in the art that these beads could be used for the removal of phage from a suspension. Therefore, it would have been obvious to those in the art that such removal would be a functional equivalent of the removal or inactivation of the phage as is taught by Wilson. Because the removal method suggested by Olsvik would have been recognized as an obvious alternative method for the removal of phage from the method in Wilson, it would have been obvious to those in the art to have used magnetic beads for the removal of virus from the samples.

Additionally, the art also teaches that one method of using the beads to bind to the phage is through attaching biotin to the phage, and streptavidin to the beads such that when the two are brought into contact the phage forms a complex with the bead. See e.g., Sun et al., pages 273-74 (section entitled "Construction of bacteriophage-based biosorbent"). It would therefore have been obvious to those in the art to use biotinylated phage as the first phage in the method of Wilson, and to use streptavidin coated beads for their removal. In view of these teachings, the currently claimed methods would have been obvious variants of the method described by Wilson.

10. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Wilson, Olsvik, and Sun as applied above, and further in view of Teodorescu et al. (U.S. 4,797,363- of record in the April 2004 IDS). Claim 7 further limits the method of claim 1 to embodiments of the method wherein the new bacteriophage are detected through the use of a fluorescent dye or nanocrystal. Claim 8 requires that the detection be made through the use of a light microscope. The teachings of the Wilson, Olsvik, and Sun references have been described above. These references doe not teach the detection of the new phage through the use of fluorescent dyes.

However, the Teodorescu reference teaches the use of phage as identification agents in methods of detecting biological structures. The reference teaches that the presence of bound phage may be visualized through conjugation of the phage to a visualizing agent, which may be a fluorescent dye. Column 3, esp. lines 60-64. The reference teaches that such dyes may be detected through the use of a light microscope. See e.g., Column 9, lines 43-65. Because the reference teaches that the labeling of phage with such dyes allows for their presence to be detected, it would have been apparent to those in the art that such a method of detecting the phage is a functional equivalent of the plaque assay method used in Wilson. It would therefore have been obvious to those in the art to substitute the fluorescence-based method of detection for the plaque assay. Thus, the combined teachings of these references render obvious the claimed methods of detecting bacterial cells.

11. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Wilson, Olsvik, and Sun as applied above, and further in view of Yazdankhah et al. (Vet Microbiol 62:17-26- of record in the April 2004 IDS). For the purpose of this rejection, it is assumed that the binding agent of claim 15 is the same binding agent described in claim 5 (i.e. the binding agent for the first phage). These claims describe the method of the claims above, wherein the new bacteriophage are detected by complexing the new phage with a substrate comprising an immobilized binding agent to the new phage, and detecting the phage/substrate complex. The teachings of Wilson, Olsvik, and Sun have been described above. The references above do not specifically teach the use of a second substrate to detect the new phage. Additionally, the Wilson reference teaches an alternative means (plaque assay) of detecting the new phage.

However, as was described above, the Olsvik reference teaches that the beads may be used in the detection of viruses. Page 43. Additionally, the Yazdankhah reference teaches a method for the detection of bacteria through the conjugation of a bead to an antibody, and the use of the conjugated bead/antibody in a sandwich assay for the target bacterium. From these teachings, it would have been obvious to those in the art that the bead/antibody binding agent conjugate could also be adapted to detect phage. As the use of such beads for the detection of phage was known in the art, and would have been recognized as an alternative to the plaque assay for the detection of the new phage, it would have been obvious to those in the art to substitute such a method for the detection of the new phage for the plaque assay used in the method of Wilson. The teachings of these references therefore render the indicated claims obvious.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

James C. Housel
JAMES HOUSEL 12/13/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600